

INDUSTRY SUB-SECTOR REPORT: PHARMACEUTICALS

SUMMARY

In recent years, the Romanian market for pharmaceuticals has seen an average annual growth of 16%, reaching slightly over \$1 billion in 2004. Annual spending on pharmaceuticals amounted to about 40% of the total national health budget. Approximately 57% of the pharmaceuticals used in Romania are imported. The principal foreign players active in Romania are Glaxo-SmithKline, Sanofi-Aventis, Hoffmann La Roche, Pfizer, Servier, Sandoz, Novartis, Schering Plough, Eli Lilly, and Merck Sharp & Dohme. New good-quality foreign products compete successfully with the best-selling domestic drugs when supported by aggressive advertising campaigns. The United States, which has historically been viewed as an important manufacturer of high-quality products, holds approximately 16% of the total Romanian market for pharmaceuticals. The market is expected to continue to expand, as is the percentage of the market held by US firms. The roadmap for entering this market indicates that U.S. companies utilizing creative strategies stand good a chance of becoming important players in the Romanian pharmaceuticals market.

MARKET OVERVIEW

In 2004, the Romanian market for pharmaceuticals amounted to more than \$1 billion. In recent years, it has recorded an average annual growth rate of 16%. Analysts expect the growth rate to continue to expand, mainly due to an anticipated increase in per-capita income as a result of healthy economic development.

Approximately 40% of Romania's total national health budget for 2004 was spent on pharmaceuticals. Domestic production covered about 43% of the demand for pharmaceuticals. The Romanian drug industry has relatively low productivity due to the labor-intensive nature of the industry coupled with the problems generated by the scarcity of modern equipment. Despite the fact the sector has been almost completely privatized problems continue.

The most important factor affecting the market in recent years has been pricing, which is not unusual for a country in which a large portion of the population survives on very wages. The price-sensitivity of the pharmaceutical market has generated high demand for domestically produced pharmaceuticals, which represent a more affordable option for low-income users.

In spite of this situation, imports of pharmaceuticals have consistently increased in recent years. In 2004, total imports accounted for 57% of the Romanian market for pharmaceuticals, while imports from the United States accounted for about 16% of the total market. Both doctors and mid-to-high-income patients prefer to use brand-name drugs because they are thought to offer the guarantee of better quality and higher efficiency than those of similar Romanian-manufactured options.

MARKET TRENDS

Recent Romanian political programs have paid special attention to the development of the healthcare system and to possible improvements in its financing. Every year special funds are allocated from the national budget (through the Ministry of Health) as well as from the health insurance budget to finance such healthcare programs as those aimed at controlling HIV/AIDS, diabetes, cancer, and psychiatric diseases. The projected increase in GDP over the next years is expected to lead to increases in the national health budget, which will channel more funds to specific national health programs and investments in healthcare facilities.

The health insurance system is supervised by the National Health Insurance House (NHIH), which also co-operates with the Ministry of Health and the Ministry of Finances in the coordination and financing of healthcare programs. Healthcare funds are collected by the NHIH mainly through mandatory contributions from individuals and legal entities. These funds are used for the reimbursement of the providers of healthcare services (doctors, pharmacies, hospitals, etc.) and for the financing of healthcare programs.

Healthcare programs developed as part of a more efficient implementation of both national and private health insurance programs are expected to offer considerable business opportunities for domestic and foreign players on the Romanian pharmaceuticals market.

The market will also be strongly influenced by the notable interest in investors focused on constructing more private hospitals, clinics, and health centers, as well as by the trend of foreign drug companies establishing manufacturing facilities in Romania.

Importantly, the market is expected to be favorably influenced by mandatory legislative changes required in preparation for Romania's joining the European Union as of January 1, 2007. This will make the Romanian pharmaceutical market more predictable, better protected, and friendlier for foreign investors.

IMPORT MARKET

Imports accounted for 57% of the Romanian market for pharmaceuticals in 2004. The main drug exporters to Romania are Western European companies, which have used aggressive promotion and qualified local consultants to penetrate the market. Among the largest exporters to Romania (each showing an export value of more than \$1 million), 42 are West European, nine American, four Central and Eastern European, two Egyptian, and one Japanese. The Romanian import market for pharmaceuticals also includes a large number of small producers that work through a wide network of distributors.

Major imports come from: GlaxoSmithKline (7.1%), Sanofi Aventis (6.1%), Hoffmann La Roche (5.8%), Pfizer (5.3%), Novartis (4.4%), Schering Plough (2.7%), Eli Lilly (2.6%), and Servier (2.5%).

Imported products with the best sales potential include OTC products (vitamins, dietetic agents, anti-inflammatory and anti-rheumatic products, antacids, anti-flatulents and anti-ulcerants, anti-anaemic preparations); drugs used to treat diabetes and cerebral and peripheral vasotherapeutics; psycholeptics; bronchodilators and anti-asthma preparations; systemic antibiotics and antiviral; anticoagulants; immunostimulating agents; anaesthetics; systemic corticosteroids; and hospital products.

COMPETITION

Local production has lost a competitive advantage during the last ten years, and export sales have declined. Currently, the share of the market covered by domestic production is estimated at about 43%. The introduction of Good Manufacturing Practice (GMP) as of January 1, 2004, has put the quality of the Romanian pharmaceutical industry to a test, and the disappearance of some small producers is anticipated. The principal pharmaceuticals produced domestically include antibiotics, vitamin and mineral supplies, analgesics, and myocardial therapy drugs. A revival of domestic production may be generated by foreign investment, resulting in a technological upgrade of existing factories, and license acquisitions.

Competition among drug exporters to Romania is extremely fierce. Western European companies, which have used aggressive promotion and highly qualified local consultants to penetrate the market, are the strongest players in the Romanian import market for pharmaceuticals.

The United States, which is typically considered an important manufacturer of high-quality products, holds approximately 16% of the total Romanian market for pharmaceuticals. The main American pharmaceutical manufacturers active in Romania are Pfizer (5.3%), Schering Plough (2.7%), Eli Lilly (2.6%), Merck Sharp&Dohme (1.7%), Abbott Laboratories (1.2%), and Bristol-Myers Squibb (1.2%).

New highly efficient U.S. products, supported by aggressive advertising campaigns, currently successfully compete, and are expected to continue to compete, with the best-selling domestic and third-country drugs. There is a growing need in Romania for new products and innovative therapy, especially in the areas of cardiovascular and respiratory diseases, oncology and hematology. Qualified U.S. drug manufacturers would be well-advised to use this market niche to expand their business in Romania.

To further penetrate the market, U.S. companies should consider joint ventures and cooperative ventures with Romanian companies.

END USERS

The principal end-users of pharmaceuticals are hospitals and pharmacies. Currently, more than 90% of Romanian hospitals are still state-owned. Healthcare in state-owned units is free for Romanian citizens. Patients who patronize private clinics pay full prices. While Government expenditures on public hospitals have declined significantly

during the last ten years, new demand for pharmaceuticals is attributable to the strong growth of private clinics offering outpatient surgery and laboratory testing. These clinics are funded through cash payments, as there are no private health insurance programs in Romania at this time.

Price is the main factor considered when purchasing. Medical representatives hired by drug manufacturers or distributors manage to offset that effect on market penetration by offering higher-priced good-quality products.

The bargaining power of hospitals is at the moment inexistent. The government stipulates that the tenders be used for procurement of pharmaceuticals and hospital products. A tender system is also used for all public-health programs.

Pharmacies have considerable bargaining power due to favorable legislation, strong professional solidarity, and fierce competition among distributors with similar offers. Romanian law permits the operation of pharmacy chains, which are very lucrative accounts enjoying even greater bargaining power. As a result, the distributor's mark-up as well as a percentage of the importer's of the mark-up are absorbed by pharmacies.

MARKET ACCESS

Certification, safety standards: With the 2007 goal for Romania's integration into the European Union, all regulations and practices are gradually changing to comply with EU standards. Drug manufacturers must apply for registration of their products with the National Drug Agency. If the drug commission named by the authorities approves the application, the registration procedure takes between 12 and 24 months and the drugs are checked for conformity with analysis certificates submitted within the registration dossiers. If drugs are to be introduced into the EU-member country by the World Bank, the registration time is drastically reduced. All drugs possessing certificates of registration from the European Medicine Evaluation Agency are registered within 3 to 6 months. Registered drugs must meet the standards of Good Manufacturing Practice (GMP certificate for the manufacturer is required) and must have a free sales certificate released for the country where they are manufactured. The fee for registration with the National Drug Agency is about \$500. Legislative requirements for registration are in perfect agreement with E.U. guidelines. A Romanian sponsor, a Romanian agent/distributor, or a Romanian-based company must submit an application for registration. All new drugs introduced into the Romanian market must be registered. As of the end of 2004, about 1,000 active molecules with 3,800 brands (of which 1,254 OTC products) were registered on the Romanian market. Of the 3,800 brands, 33% (1,269) were Romanian. The Control Department of the National Drug Agency is responsible for monitoring drug quality, inspecting production facilities and issuing GMP certificates. The GMP certificate must be renewed every other year.

Labeling requirements: All drug labels and leaflets regarding pharmaceuticals must be translated into Romanian.

Duty rates: Duty rates that apply to pharmaceuticals are between 0 and 15%. An importer's margin of 15% and a devaluation risk margin of 5% are applicable. The Value Added Tax (VAT) rate for drugs is currently 9%. The position of the Romanian national currency (Leu) vs. the U.S. dollar has experienced marked improvement, and experts expect the Romanian financial market to continue to be stable.

Pricing Policy: The Ministry of Health is the entity responsible for establishing norms regulating the pricing of both imported and domestically produced drugs. According to existing regulations, the Ministry may adjust the price of domestic drugs periodically, based on a comparison to 12 countries and by selecting the lowest price. There are no norms with regard to the exchange rate used or with regard to the official data used by the Ministry. The Ministry of Health must be notified regarding any price adjustments.

The margins that wholesalers and retailers together may charge end-users cannot exceed 33%. The mark-up for domestic drugs is listed as a percentage of the producer price and is divided between distributors (4-9%) and pharmacies (10-24%).

With regard to imported drugs, mark-ups are listed as a percentage of the value obtained by calculating the drug's price in Romanian currency (the invoice price multiplied by the exchange rate on the date the custom documents are issued), customs duties (0-15%), VAT (9%), the importer's margin (15%) and the devaluation risk margin (5%). The split between wholesalers and pharmacies' margins is also applicable for imported drugs.

The fact that outpatients are entitled to subsidized drugs from a list compiled by the Ministry of Health and the NHIH, based on recommendations made by the College of Physicians, has created problems for everyone in the Romanian pharmaceuticals market. Despite efforts aimed at streamlining the entire process, reimbursement to the drug suppliers remains characterized by massive delays that severely affect manufacturers, distributors, and pharmacies alike, creating liquidity constraints within the industry.

MARKET ENTRY

American firms interested in entering the Romanian market for pharmaceuticals should consider working with their local Export Assistance Center and the Commercial Service in Bucharest in order to locate the most useful contacts, identify the most efficient distribution and media channels, and apply the best strategies at any given moment.

Drug exporters have at their disposal a wide network of distribution channels in the Romanian market, encompassing more than 500 active drug distributors. The following ten distributors account for more than 70% of the market: Europharm, Relad International, Mediplus Exim, Polisoano, Fildas Trading, Montero, Sindan, Farmexim, Dita Import Export, and Tamisa Trading. Distributor expertise plays an essential role in guiding a potential foreign supplier through the bureaucratic maze of market entry.

Potential investors in the Romanian pharmaceutical manufacturing industry should be aware of the fact that this industry possesses well-trained specialists and large capacities

for increased manufacturing. Production costs that are much lower than in Western Europe are the main incentive for a foreign drug manufacturer to use local production facilities and invest in their development. Solid documentation on the local drug manufacturing industry is needed in order for a potential foreign investor to make the best decision on the type of investment, financing strategies, and funding sources for long-term projects. Using the services of a good consulting company and making direct contact with industry specialists are mandatory to ensure the success of this type of investment.

Opportunities for Profile Building

Networking opportunities for exporters are offered by events organized by such professional associations as the Romanian Association of International Drug Manufacturers and the Romanian Association of International Drug Distributors. There are also a number of medical publications with fairly large circulations that can help build an exporter's profile (see list below).

Key Contacts

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Upcoming Trade Events

Denta (November 16-19, 2005)
Denta (March 8-11, 2006)
Rom Medica (April 5-8, 2006)
Rom Pharma (April 5-8, 2006)
Rom Optic (April 5-8, 2006)

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